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IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF NEW JERSEY

ARAGON PHARMACEUTICALS, INC.,  
JANSSEN BIOTECH, INC., and SLOAN-  
KETTERING INSTITUTE FOR CANCER  
RESEARCH,

Plaintiffs,

v.

LUPIN LIMITED and LUPIN  
PHARMACEUTICALS, INC.,

Defendants.

Honorable Stanley R. Chesler, U.S.D.J.  
Civil Action No. 2:22-CV-2825(SRC)(LDW)

**STIPULATED ORDER AND JUDGMENT ON PLAINTIFFS' CLAIMS OF  
INFRINGEMENT OF U.S. PATENT NO. 9,481,663**

**WHEREAS**, Plaintiffs Aragon Pharmaceuticals, Inc., Janssen Biotech, Inc., and Sloan-Kettering Institute for Cancer Research (collectively, "Plaintiffs") filed a Complaint, a First Amended Complaint, and a Second Amended Complaint (Civ. No. 2:22-CV-2825) against Defendants Lupin Limited and Lupin Pharmaceuticals, Inc. (collectively, "Defendants") alleging that "the submission of Abbreviated New Drug Application No. 217084 ('the ANDA') by Defendants to the United States Food and Drug Administration ('FDA') seeking approval to market a proposed generic version of Erleada<sup>®</sup> ('Proposed ANDA Product') prior to the expiration of" U.S. Patent No. 9,481,663 ("the '663 patent") infringed the '663 patent, and that Defendants will infringe the '663 patent by making, using, selling, offering to sell within the United States, and/or importing into the United States Defendants' Proposed ANDA Product;

**WHEREAS**, Defendants have asserted counterclaims that the '663 patent is invalid, unenforceable, and/or not infringed;

**WHEREAS**, Defendants produced to Plaintiffs drug product batches ending in batch numbers -0061 and -0062 that Defendants hereby stipulate are representative of the Proposed ANDA Product produced by the manufacturing processes set forth in ANDA No. 217084 that were disclosed to Plaintiffs on or about April 21, 2022;

**WHEREAS**, on September 12, 2023, Plaintiffs informed Defendants that they would not continue to assert the '663 patent against Defendants in view of Plaintiffs' analysis of the drug product batches ending in batch numbers -0061 and -0062 that were made by the manufacturing processes set forth in ANDA No. 217084 that were disclosed to Plaintiffs on or about April 21, 2022;

**IT IS HEREBY STIPULATED AND AGREED** by and among the Parties, subject to approval of the Court, as follows:

1. Defendants have not infringed and will not infringe claims 1, 13, and/or 17, or any of the other claims of the '663 patent, by making, using, selling, offering to sell within the United States, and/or importing into the United States the Proposed ANDA Product made according to the manufacturing processes set forth in ANDA No. 217084 that were disclosed to Plaintiffs on or about April 21, 2022;
2. Defendants have not infringed claims 1, 13, and/or 17, or any of the other claims of the '663 patent, by submitting, maintaining, or causing to be submitted ANDA No. 217084 with the manufacturing processes set forth in ANDA No. 217084 that were disclosed to Plaintiffs on or about April 21, 2022;

3. Defendants dismiss their counterclaims against the '663 patent (D.I. 60, Counts I and II);
4. Pursuant to paragraphs 1 and 2 above, judgment of noninfringement with prejudice is hereby entered in favor of Defendants and against Plaintiffs on Count I of Plaintiffs' operative Second Amended Complaint (D.I. 59);
5. This stipulated judgment does not affect Plaintiffs' ability to reassert the '663 patent against Defendants if Defendants have altered, or do alter the manufacturing processes for the Proposed ANDA Product set forth in ANDA No. 217084 that were disclosed to Plaintiffs on or about April 21, 2022, in a manner that results in the polymorph claimed in the '663 patent, nor does this stipulation affect Defendants' ability to reassert its counterclaims that the '663 patent is invalid, unenforceable, and not infringed should Plaintiffs reassert the '663 patent due to any such alteration; and
6. Each party will bear its own attorneys' fees and costs in connection with the claims and defenses concerning the '663 patent up to the date of the entry of this stipulated judgment.

IT IS SO STIPULATED:

Dated: December 6, 2023

s/ Keith J. Miller

Keith J. Miller, Esq.  
Michael J. Gesualdo, Esq.  
**ROBINSON MILLER LLC**  
Ironside Newark

Respectfully Submitted,

s/ James S. Richter

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Lupin Pharmaceuticals, Inc.*

*Aragon Pharmaceuticals, Inc., Janssen  
Biotech, Inc., The Regents of the University  
of California, and Sloan-Kettering Institute  
for Cancer Research*

IT IS SO ORDERED this 11<sup>th</sup> day of December, 2023.

s/ Stanley R. Chesler

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~~HONORABLE WALTER S. MCMILLAN~~